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| EXAMINER | |
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| REIDEL, JESSICA L | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/731,892 | SHEFFIELD ET AL. | |
| | Examiner | Art Unit | |
| | JESSICA REIDEL | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-7,9-23,25-27,32-43,45-55,61-70,72-76 and 78-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *74 and 82* is/are allowed.

6)☒ Claim(s) *1,4-7,9-12,14-23,25-27,32-43,45-57,61-70,72,73,75-81 and 83-89* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

2. Applicant's submission filed on April 7, 2008 has been entered. Claims 2, 3, 8, 24, 28-31, 44, 56-60, 71 and 77 are cancelled. Claims 87-89 are new and have been added. Claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70, 72-76 and 78-89 are pending.

### *Information Disclosure Statement*

3. The information disclosure statement (IDS) submitted on April 28, 2008 has been acknowledged and is being considered by the Examiner.

4. Applicant should note that the large number of references (both previously and newly submitted) have been considered by the Examiner in the same manner as other documents in Office search files are considered by the Examiner while conducting a search of the prior art in a proper field of search. See MPEP § 609.05(b). As previously requested in the Final Rejection of May 4, 2007, Applicant is again respectfully requested to point out any particular references which they believe may be of particular relevance to the instant claimed invention. Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

> Although a concise explanation of the relevance of the information is not required for English language information, Applicants are encouraged to provide a concise explanation of why the English-language information is being submitted and how it is understood to be relevant. Concise explanations (especially those which point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and Applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and Applicant is aware that one or more are highly relevant to patentability. MPEP § 609.04(a).

5. This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), stating that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id* 1888. The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

> It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972). aff'd 479 F.2d 1338 (5thCir 1974). MPEP § 2004.

6. Therefore, it is recommended that if any information that has been cited by Applicants is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents in an effort to expedite prosecution of the current application.

### *Specification*

7. In view of the amendments made to the abstract (filed July 5, 2007), the objection(s) applied against the disclosure in the Final Rejection of May 4, 2007 have been withdrawn.

### *Claim Objections*

8. Claims 76 and 89 are objected to because of the following informalities: inadvertent typographical errors exist. As to Claim 76, line 9, the Examiner suggests changing "identifying a second language-based task subject to a language disorder" to read, "directing the patient to perform a second language-based task" instead. The Examiner references Claims 17, 18, 55, 75 which recite similar limitations as a basis for such suggestions. Appropriate correction is required in order to avoid confusion and to ensure that the method of Claim 76 is distinctly and particularly defined. As to Claim 89, line 2, the Examiner suggests changing "to the cortical input" to read, "to the cortical inputs" instead in order to remain consistent with limitations previously presented by Claim 88. Appropriate correction is required.

### *Allowable Subject Matter*

9. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claim 48 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action (see below) and to include all of the limitations of the base claim and any intervening claims.

11. Claims 74 and 82 are allowed.

### *Claim Rejections - 35 USC § 112*

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 40-43 and 45-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 recites the limitation ""the location of all the stimulation sites for receiving electrical stimulation at the patient's brain being based" in lines 8-10 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 41, 42 and 45-55 depend from Claim 40 and the deficiencies of Claim 40 are imputed to all dependant claims.

### *Claim Rejections - 35 USC § 102*

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

15. ***Claims 19, 20, 25, 26, 32, 35-38, 78, 79, 86, 88 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Firlik et al. (U.S. 2002/0091419) (herein Firlik '419).*** As to Claims 19, 20, 35-37, 78, 79 and 86, Firlik expressly discloses methods of and systems for treating brain damage, brain disease, and/or brain disorders, including expressive language disorders and/or language comprehension disorders. In one embodiment (see Firlik '419 Fig. 1C), method 100 comprises selecting a stimulation site of a patient's brain by imaging the brain

to locate regions where neuroplasticity is occurring, the stimulation site being located within the patient's skull 700, proximate the dura mater 706, and outside a cortical surface 709 of the patient's brain (diagnostic procedure 102), and implanting first and second electrodes 660 at the stimulation site (implanting procedure 104). Method 100 further comprises coupling the electrodes 660 to a pulse system, read as a source of electrical potential 630 and reducing and/or eliminating the effects of a language disorder by applying electrical stimulation directly to the stimulation site via electrodes 660 (stimulating procedure 106).

In another embodiment (see Firlik '419 Fig. 4A), method 100a comprises selecting a stimulation site of a patient's brain according to a specific anatomic location (with or without imaging), the stimulation site being located within the patient's skull 700, proximate the dura mater 706, and outside a cortical surface 709 of the patient's brain (selecting procedure 112a), and implanting first and second electrodes 660 at the stimulation site (positioning procedure 114a). Method 100a also comprises coupling the electrodes 660 to a pulse system 630 and reducing and/or eliminating the effects of a language disorder by applying electrical stimulation directly to the stimulation site via electrodes 660 (stimulating procedure 116a) (see Firlik '419 Fig. 1C, Fig. 4A, Fig. 6 and Fig. 7, page 4, paragraphs 59-60, page 5, paragraphs 64-65, pages 6-7, paragraphs 69-83, page 8, paragraphs 85-91 and pages 10-11, paragraphs 102-108). Firlik '419 specifies that for either method 100 or 100a, the patient may or may not be actively engaged in a function-based task (i.e. language-based task) or physical therapy task while the electrical stimulation is applied. In particular, Firlik '419 discloses that the methods may involve "enhancing or inducing neuroplasticity" such that stimulation increases the probability that neurons of the stimulated site will fire when intrinsic triggers or other causes of activation (i.e. therapy) occur (see, for example, Firlik '419 page 7, paragraph 77, page 8, paragraph 86, page 9, paragraphs 96-99).

16. As to Claim 25, the methods as disclosed by Firlik '419, enhance a change in the neural activity at the stimulation site to assist the brain in performing a particular neural function (i.e. movement of a limb, learning a particular task, or producing and/or comprehending language) that may be damaged or lost due to brain damage, brain disease, and/or a brain disorder. Accordingly, and since Firlik '419 specifies that the electrical stimulation "for carrying out a particular therapy can be adapted to either increase or decrease the particular neural activity that

produces the desired results" and that the methods "are to be particularly useful for rehabilitating a loss of mental functions, motor functions and/or sensory functions cause by damage to the brain", it is inherent that the methods for treating a language disorder of a patient include reducing an aphasia of the patient by applying the electrical stimulation directly to the selected stimulation site (see Firlik '419 page 4, paragraphs 57-60 and page 8, paragraphs 87-91).

17. As to Claim 26, in addition to the arguments previously presented, the Examiner considers applying electrical stimulation to any area of the brain synonymous with applying electrical stimulation "at least proximate" to at least one of Broca's area, Wemicke's area and neuronal connections extending between Broca's area and Wemicke's area, with "at least proximate" meaning "relatively near". In addition, Firlik '419 expressly discloses that the methods may include applying an electrical stimulation at Boca's area of the inferior fontal lobe of the cortex (for treating expressive language disorders) and/or applying an electrical stimulation at Wernicke's area of the parietal lobe of the cortex (for language comprehension disorders (see Firlik '419 pages 7-8, paragraph 83-84).

18. As to Claim 32, the methods of Firlik '419 may further comprise administering a neuroexcitatory drug to the patient (e.g., an amphetamine) and applying the electrical stimulation while the drug is active in the patient's body (see, for example, Firlik '419 page 1, paragraph 4, page 6, paragraph 73 and page 8, paragraph 89).

19. As to Claim 38, Firlik '419 expressly discloses that applying the electrical stimulation may include applying a varying electrical stimulation signal having a frequency of from about 5 Hz to about 200 Hz (see Firlik '419 pages 8-9, paragraph 92).

20. As to Claims 88 and 89, method 100 of Firlik '419 includes a diagnostic procedure 102 that includes selecting a stimulation site of a patient's brain by imaging the brain to locate regions where neuroplasticity is occurring, as previously discussed. Firlik '419 expressly discloses that the diagnostic procedure 102 is used "to determine the region of the brain where stimulation will likely effectuate the desired function, such as rehabilitating a loss of a neural-function caused by stroke, trauma, disease or other circumstance". In particular, the diagnostic procedure 102 identifies a specific cortical neural population (brain region) that affects a specific neural-function (i.e. producing language or comprehending language) for determining a plurality of potential stimulation sites (see Firlik '419 Figs. 2-4 and page 5, paragraphs 66-68). As

previously discussed, electrodes 660 are implanted such that they contact the desired portion of the brain at a selected stimulation site for focusing the electrical stimulation in desired directions and/or orientations (see Firlik '419 pages 10, paragraphs 102-106 and page 13, paragraph 127).

In the alternative, method 100a of Firlik '419 includes a selecting procedure 112a that includes selecting a stimulation site of a patient's brain according to specific anatomic locations (with or without imaging). Firlik '419 expressly discloses that the selecting procedure 112a includes selecting a site at an anatomical feature of the cortex where a desired neural-activity is suspected of occurring or is expected to begin occurring. In particular, the procedure 112a comprises identifying a specific cortical neural population that affects a specific neural-function (i.e. producing language or comprehending language) for determining a plurality of potential stimulation sites (see Firlik '419 Figs. 4A-4B and page 7, paragraphs 78-83). As previously discussed, electrodes 660 are implanted such that they contact the desired portion of the brain at a selected stimulation site for focusing the electrical stimulation in desired directions and/or orientations (see Firlik '419 pages 10, paragraphs 102-106 and page 13, paragraph 127).

***Claim Rejections - 35 USC § 103***

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

22. ***Claims 22, 23, 27, 33, 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Firlik '419.*** As to Claims 22 and 23, Firlik '419 discloses the essential features of the claimed invention, as previously discussed, but does not expressly disclose that the electrical stimulation include applying the electrical stimulation to either the right or left hemisphere of the brain.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Firlik '419 to apply the electrical stimulation to either the left or right hemisphere of the brain, because Applicant has not disclosed that applying stimulation at either location provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the methods of Firlik '419, and Applicant's invention, to perform equally well with either the stimulation applied proximate the dura mater and outside a

cortical surface of a patient's brain as taught by Firlik '419, or with the stimulation applied at the claimed sites because both provide a means for effecting cortical stimulation for inducing neuroplasticity and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Firlik '419.

Therefore, it would have been prima facie obvious matter to modify Firlik '419 to obtain the invention as specified in Claims 22 or 23 because such modifications would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

23. As to Claim 27, Firlik '419 discloses the essential features of the claimed invention, as previously discussed, but does not expressly disclose that the electrical stimulation include applying the electrical stimulation to at least one of the middle temporal gyrus, the retrosplenial cortex and the retrosplenial cuneus of the brain.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Firlik '419 to apply the electrical stimulation to either the middle temporal gyrus, the retrosplenial cortex or the retrosplenial cuneus of the brain, because Applicant has not disclosed that applying stimulation to any of these locations provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the methods of Firlik '419, and Applicant's invention, to perform equally well with either the stimulation applied proximate the dura mater and outside a cortical surface of a patient's brain as taught by Firlik '419, or with the stimulation applied at the claimed sites because both provide a means for effecting cortical stimulation for inducing neuroplasticity and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Firlik '419.

Therefore, it would have been prima facie obvious matter to modify Firlik '419 to obtain the invention as specified in Claim 27 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

24. As to Claims 33-34, in addition to the arguments previously presented, Firlik '419 expressly discloses that the "actual electrical potential applied to electrodes implanted in the brain to achieve a subthreshold potential stimulation will vary according to the individual patient, the type of therapy, the type of electrodes, and other factors" (see, for example, Firlik '419 page 9, paragraph 95). Firlik '419 discloses the essential features of the claimed invention except that

it is not specified that the stimulation be applied below, at or about a level that causes movement, speech, or sensation in the patient. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to stimulate the patient with stimulation below, at or about a level that causes movement, speech or sensation in the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

25. As to Claim 39, Firlik '419 discloses the essential features of the claimed invention except that it is not specified that the stimulation be applied having an electrical potential of from about 0.25 volts to about 5.0 volts. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to stimulate the patient with stimulation having an electrical potential of from about 0.25 volts to about 5.0 volts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

26. ***Claims 1, 4-7, 9-12, 14-18, 21, 40-43, 45-47, 55, 72, 73, 75, 76, 80, 81, 83 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Firlik '419 in view of McDermott (U.S. 2004/0082847) and Binder (previously cited by the Examiner).*** As to Claims 1, 4-7, 9-12, 17, 18, 21, 40-43, 40-43, 45-47, 52-55, 72, 73, 75, 76, 80, 81, 83 and 87, method 100 of Firlik '419 includes a diagnostic procedure 102 that includes selecting a stimulation site of a patient's brain by imaging the brain to locate regions where neuroplasticity is occurring, as previously discussed. Firlik '419 expressly discloses that the diagnostic procedure 102 is used "to determine the region of the brain where stimulation will likely effectuate the desired function, such as rehabilitating a loss of a neural-function caused by stroke, trauma, disease or other circumstance". In particular, the diagnostic procedure 102 identifies a specific cortical neural population (brain region) that affects a specific neural-function (i.e. producing language or comprehending language) for determining a plurality of potential stimulation sites (see Firlik '419 Figs. 2-4 and page 5, paragraphs 66-68). At page 8, paragraph 90, Firlik '419 expressly discloses that, "the stimulation site can be identified by monitoring the neural activity using functional MRI" by directing the patient to perform an act that the particular disease of interest

has affected and monitoring the brain to determine whether any response neural activity is present. Firlik '419 specifies that "[a]fter identifying where the brain is recruiting additional matter, the electrical stimulation can be applied to this portion of the brain" (see Firlik '419 page 8, paragraphs 85-91).

Accordingly, diagnostic procedure 102 of method 100 comprises directing the patient to perform a task, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the task (i.e. MRI images) and selecting the stimulation site based at least in part on the information. Firlik '419 discloses the essential features of the claimed invention, as previously discussed, except that it is not explicitly stated that the method include directing the patient to perform a *language-based* task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the *language-based* task and selecting the stimulation site based at least in part on the information (emphasis added). However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Firlik '419 such that the diagnostic procedure 102 comprise directing the patient to perform a language-based task, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language-based task and selecting the stimulation site based at least in part on the information since Firlik '419 specifies that the method is applicable to treating language disorders, as previously discussed, and since it was known in the art to use functional MRI (fMRI) for mapping language areas of the brain. The Examiner cites McDermott and Binder as being just two examples that the use of fMRI is conventional and well known in the art for mapping language areas of the brain and that such fMRI procedures often include the steps of directing a patient to perform a language-based task and directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language-based task.

McDermott, for example, discloses a method of identifying one or more language regions in the brain of a subject. The method includes directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while

the patient performs the language based task and locating and/or identifying one or more language regions in the brain based at least in part on the information (see McDermott Abstract and page 2, paragraphs 16-25). McDermott also discloses that although the method is typically used in conjunction with surgery, the invention may be practiced in a variety of surgical and non-surgical environments in which it may be desirable to locate brain regions that support language (see McDermott page 1, paragraphs 6 and 15). As previously discussed, Firlik '419 discloses that it is preferable to identify the specific cortical neural populations (brain regions) that modulate the specific cognitive function that is impaired in the patent to be treated with electrical stimulation for electrode placement. McDermott discloses that it is desirable to use such functional MRI techniques for pre-operative language area mapping so that surgical electrical stimulation mapping might be avoided. McDermott further discloses that the methods disclosed utilizing such functional MRI techniques to identify the language areas of the brain are more precise then invasive techniques known in the art (see McDermott page 1, paragraph 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diagnostic procedure 102 or Firlik '419 in view of McDermott to include directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and selecting the stimulation site based at least in part on the information in order to precisely identify the cortical brain regions that modulate the specific cognitive function (such as language) that is impaired in the patient to be treated with the electrical stimulation.

Applicant differs from the modified Firlik '419 reference in that the method also includes directing the patient to repeat a noun, directing the patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands. The Examiner considers the use of these different semantic decisions and language based tasks within functional MRI screening as a means to accurately locate the language centers in the brain to be conventional and well known in the art with Binder being but on example. Binder discusses methods of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word

based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other (see Binder page 384, columns 1-2, page 385, columns 1-2, page 386, columns 1-2 and page 387, column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fMRI tasks given in the method of Firlik '419 in view of McDermott to further include the additional steps of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other in order to better the invention.

27. As to Claims 14 and 49, McDermott discloses that directing information to be collected includes directing a computer-based routine to collect and process the information (see McDermott page 3, paragraph 32 and page 4, paragraph 39).

28. As to Claims 15 and 50, McDermott further discloses that the method includes directing the formation of an image of at least a portion of the patient's brain, with at least a portion of the image having features representative of the information (see McDermott Figs. 2-5 and page 4, paragraphs 40-46).

29. As to Claims 16 and 51, McDermott discloses that two types of language function may be shown on an fMRI brain scan. With reference to McDermott Fig. 2, row 30 depicts differences in activity for the two list types at row 130 and row 230. The image includes a first region with a characteristic of the first region having a first value (regions preferentially active for the phonological task) and a second region with a characteristic of the second region having a second value different than the first value (regions preferentially active for the semantic task) (see McDermott Fig. 2 and page 4, paragraph 46).

30. ***Claims 61, 64-70, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schäffler et al. "Quantitative Comparison of Language Deficits Produced by Extraoperative Electrical Stimulation of Broca's, Wernicke's and Basal Temporal Language***

***Areas" (herein Schäffler) in view of Binder.*** Schäffler expressly discloses a method for treating a brain disorder (i.e. epilepsy) comprising directing a patient to perform a task (i.e. a language-based task), directing information to be collected, the information corresponding to a level of neural activity in the patient's brain while the patient performs the task and applying an electrical stimulation at least proximate to a stimulation site of the patient's brain while directing the information to be collected, the stimulation site being proximate the dura mater and outside a cortical surface of the patient's brain (see Schäffler entire document). Schäffler discloses the essential features of the claimed invention except that it is not specified that the method also includes directing the patient to repeat a noun, directing the patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands.

The Examiner considers the use of these different semantic decisions and language based tasks within brain mapping procedures as a means to accurately locate the language centers in the brain to be conventional and well known in the art with Binder being but on example. Binder discusses methods of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within a brain mapping proceudure (fMRI) to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other (see Binder page 384, columns 1-2, page 385, columns 1-2, page 386, columns 1-2 and page 387, column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tasks given in the method Schäffler to further include the additional steps of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other in order to better the invention.

***Response to Arguments***

31. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

32. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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